

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

This document relates to:  
*All Actions*

No. 1:19-md-2875-RBK

Hon. Robert B. Kugler  
Hon. Karen M. Williams  
Hon. Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO  
ZHP'S MOTION FOR A PROTECTIVE ORDER**

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## **INTRODUCTION**

On this motion, ZHP attempts to re-argue the question of whether the depositions of the ZHP employees in question are necessary; however, that question was previously decided in Plaintiffs' favor. This Court only granted ZHP leave to brief whether Yuelin Hu, Fengyan (Xavier) Tang, Mi (Karen) Xu, and Yanfeng (Lucy) Liu constitute "managing agents" as that term is defined in the applicable law, and if the answer is in the affirmative, then the motion must be denied. The Court should therefore limit its review to this question.

This Court has already ordered the depositions of Ms. Hu, Mr. Tang, Ms. Xu, and Ms. Liu. Notably, ZHP concedes Ms. Xu's status as its managing agent; thus, the motion must be denied as to Ms. Xu. In addition, in the spirit of compromise and efficiency, Plaintiffs hereby rescind their request to depose Yanfeng (Lucy) Liu; thus, there is no issue to address in connection with this witness. However, the Court should not take this as a concession of the merits of ZHP's motion, which is based on a conclusory declaration that is contradicted by dozens of records in its production and certainly many more in its possession. Based on the record discussed below, this Court should deny the motion as to Ms. Hu and Mr. Tang, as well as Ms. Xu.

## **PROCEDURAL HISTORY**

After reviewing the Parties' submissions on whether Plaintiffs were entitled to depose Yuelin Hu, Fengyan (Xavier) Tang, and Mi (Karen) Xu, this Court stated that "the plaintiffs have made a very good case for why these witnesses have relevant knowledge, **merely because they report to a witness that otherwise is being deposed, I don't think is a -- a good faith argument that their testimony is duplicative. . . . [I]n *Benicar*, 20 foreign depositions were permitted of Daiichi, and here, plaintiff is proposing to take 20 depositions of U.S. and foreign ZHP."**

(12/22/2020 Trans. 40:14-22, Ex. 1).<sup>1&2</sup> The Court confirmed this ruling in its December 31, 2020 order: “[P]laintiffs are granted leave to depose Y. Hu, Y. Liu, F. Tang, [and] M Xu.” (Order ¶ 3, ECF 704, Ex. 2). In response to ZHP’s subsequent argument that these witnesses were not subject to deposition under Federal Rule of Civil Procedure 30(b)(1), the Court granted ZHP “leave to serve a supplemental letter brief regarding *whether it is required to produce the disputed witnesses for deposition or whether plaintiffs are required to serve the witnesses with subpoenas or other required process.*” (01/11/2021 Order ¶ 4, ECF 727, Ex. 3). ZHP’s then filed its motion for a protective order.

## LEGAL ARGUMENT

### I.

#### **THE DEPONENTS ARE ZHP’S MANAGING AGENTS**

A protective order can only be entered where the moving party establishes that “there exists a likelihood that the resulting benefits [of the discovery] would be outweighed by the burden or expenses imposed as a consequence of the discovery after assessing the following factors: (1) the unreasonably cumulative or duplicative effect of the discovery; (ii) whether the party seeking discovery has had ample opportunity to obtain the information by other discovery; and (iii) the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at

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<sup>1</sup> Unless otherwise noted, the exhibits cited in this brief are attached hereto. For the convenience of the Court, Plaintiffs have removed pages of the exhibits to focus the Court’s attention on the portions relied upon in this brief.

<sup>2</sup> In *Benicar*, the plaintiffs took “at least twenty (20) depositions of present and former Daiichi U.S. employees and eighteen (18) depositions of present and former Daiichi Japan employees.” No. 15-md-2606 (RBK/JS), 2016 WL 6652358, at \*1 (D.N.J. Nov. 9, 2016) (Ex. 46). In this case, taking in account Plaintiffs’ rescinding their request to depose Yanfeng (Lucy) Liu, the Court has ordered a total of nineteen depositions of ZHP affiliates: five employees of ZHP’s U.S. subsidiaries, one employee of both the U.S. subsidiaries and ZHP itself, and thirteen employees of ZHP or one of its Chinese subsidiaries.

stake in the action, and the importance of the discovery in resolving the issues.” *Campbell v. Sedwick Detert, Moran & Arnold*, Civ. No. 11-642, 2013 WL 1314429, \*8 (D.N.J. Mar. 28, 2013) (Ex. 5) (citing Fed. R. Civ. Proc. 26(b)(2)(C)). That standard is not met here, and the motion should be denied.

The Parties agree that “[u]nder Rule 30(b)(1) a witness may be noticed for a deposition to provide testimony on behalf of a corporation if the witness is an officer, director, or managing agent of the corporation.” (Def.’s Br. 9, citing *In re: Benicar (Olmesartan) Prod. Litig.*, No. 15-2606 (RBK/JS), 2016 WL 5817262, at \*4 (D.N.J. Oct. 4, 2016) (Ex. 4); *Campbell*, 2013 WL 1314429, at \*12).

In *Benicar*, the Court noted that “[w]hether an individual is a ‘managing agent’ is to be determined ‘pragmatically on an ad hoc basis.’” 2016 WL 5817262, at \*3 n.12 (quoting 8A Charles Alan Wright et al., *Federal Practice and Procedure* § 2103 (3d ed. 2016)). Courts consider several factors when making this determination:

- (1) “[Whether] the individual involved is invested by the corporation with general powers to exercise his discretion and judgment in dealing with corporate matters,”
- (2) “[W]hether he or she can be depended upon to carry out the employer's direction to give testimony at the demand of a party engaged in litigation with the employer, and”<sup>3</sup>
- (3) “[W]hether he or she can be expected to identify with the interests of the corporation rather than with those of the other parties.”<sup>4</sup>

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<sup>3</sup> ZHP argues that this factor is not satisfied for Ms. Hu and Mr. Tang because their depositions cannot legally take place in China. However, these depositions will take place in Hong Kong, as ordered by the Court. (12/30/2020 Order ¶ 10, ECF 701, Ex. 6).

<sup>4</sup> Inexplicably, ZHP argues that this factor cannot be met Ms. Hu and Mr. Tang because “the factual record is undeveloped at this stage,” ignoring the fact that these witnesses are employed by ZHP and ZHP has access to all of their knowledge and documents. (Def.’s Br. 18). ZHP asked

*Id.* (quoting Wright, *Federal Practice and Procedure* § 2103). The first factor includes the employee's "general responsibilities, **particularly with regard to the matters at issue in the litigation.**" *Campbell*, 2013 WL 1314429, at \*14 (citing *Triple Crown America, Inc. v. Biosynth AG*, Civil No. 96–7476, 1998 WL 227886, at \*2 (E.D. Pa. Apr. 30, 1998) (citing *Founding Church of Scientology*, 802 F.2d 1448, 1453 (D.C. Cir. 1986); *In re Honda American Motor Co., Inc. Dealership Relations Litig.*, 168 F.R.D. 535, 540–41 (D. Md. 1996))). **"Doubts regarding an individual's status as a 'managing agent' are resolved in favor of the examining party."** *Id.* at \*14 (citing *Founding Church of Scientology*, 802 F.2d at 1452; *In re Honda*, 168 F.R.D. at 540–41).

**A. Yuelin Hu is ZHP's Managing Agent**

ZHP's motion relies almost entirely on the conclusory Declaration of Wang Ma.<sup>5</sup> (Def.'s Ex. E). To be clear, the Declaration is essentially a negated restatement of the managing agent test with Ms. Hu's name inserted: "Ms. Hu does not have independent decision making authority to bind ZHP without sign off from a supervisor," and "Ms. Hu would not be expected to represent ZHP or to speak on behalf of ZHP on corporate matters or valsartan manufacturing, quality, sales, or regulatory issues." (Def.'s Ex. E). *See In re: Benicar*, 2016 WL 5817262, at \*3 n.12 (quoting

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the Court for leave to file this motion knowing that none of its employees had been deposed yet. It cannot ask this Court to grant its motion because it decided to do so at this stage of the litigation. Moreover, this factor is met for Ms. Hu and Mr. Tang, as explained below.

<sup>5</sup> ZHP provides two business records in support of its motion regarding Ms. Hu. The first is an outdated organization chart stating her title is "QA Manager." (Def.'s Ex. F). However, ZHP promoted Ms. Hu to Assistant Director of Quality Assurance over three years ago in January 2018. (ZHP00292071, Ex. 7). The second document shows Ms. Hu reporting to the Cunxiao (Jenson) Ye, whom ZHP acknowledges no longer works for the company. (Def.'s Ex. G; Def.'s Br. 14). The Court should not rely on either of these documents in deciding this motion. Plaintiffs also note that ZHP has designated these documents "Confidential." However, they contain no information that would conceivably meet that definition under this case's Confidentiality and Protective Order. (06/26/2019 Order ¶ 9.B, Ex. 47).

Wright et al., *Federal Practice and Procedure* § 2103). Dozens of records in ZHP's production and certainly many more in its possession contradict the Declaration and prove that Ms. Hu is ZHP's managing agent.

Preliminarily, the Declaration does not provide Ms. Hu's title (Assistant Director of Quality Assurance) or a comprehensive list of her responsibilities. According to a document approved by Ms. Hu herself, quality assurance at ZHP has the following "[r]esponsibilities/[a]uthority":

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]



■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

(ZHP00291951-53, Ex. 7). These responsibilities concern some of the most important issues in this case. As such, they are particularly relevant to this analysis. *See Campbell*, 2013 WL 1314429, at \*14 (citing *Triple Crown America*, Civil No. 96-7476, 1998 WL 227886, at \*2 (citing *Founding Church of Scientology*, 802 F.2d at 1453; *In re Honda*, 168 F.R.D. at 540-41)). As

explained below, ZHP's documents show that Ms. Hu executed these responsibilities on its behalf and without the review of a superior both internally and externally on a regular basis.

Ms. Hu's authoritative involvement in the nitrosamine contamination starts at its root cause in 2011. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].<sup>6</sup> As the Court knows, ZHP's violations of cGMPs are central to this case.

*In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, MDL No. 2875 (RBK/KW), 2021 WL 307486, at \*11 (D.N.J. Jan. 29, 2021) (Ex. 59).

However, Ms. Hu's involvement and authority over the manufacture of ZHP's contaminated valsartan did not end there. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>6</sup> As a Chinese company, ZHP obviously produces most documents in Chinese. For regulatory purposes and in response to the nitrosamine contamination, ZHP translated many of its documents into English. This is an example of such a document, which is why it is entirely typed and lacks real signatures. In some case, English documents leave signatures entirely blank. (*Compare* ZHP00332358, Ex. 10, *with* ZHP00330625, Ex. 48).

[REDACTED]

[REDACTED] For context, “[r]evaluation of any [pharmaceutical manufacturing] process is an essential part of the validation. It improves the quality of the product and increases the smoothness of the process. There are various conditions in which it is essential to revalidate the process. Revalidation is in two conditions[:] A. Periodic Revalidation [and] B. Revalidation after any change.” Ankur Choudhary, *Revalidation of Pharmaceutical Processes*, Pharmaceutical Guidelines, <https://www.pharmaguideline.com/2014/07/revalidation-of-pharmaceutical-processes.html>.

Unfortunately, Ms. Hu’s re-validation protocol obviously failed to serve its purpose, amplifying the need for her testimony.

[REDACTED]

[REDACTED] See *Campbell*, 2013 WL 1314429, at \*14 (citing *Triple Crown America*, Civil No. 96–7476, 1998 WL 227886, at \*2 (citing *Founding Church of Scientology*, 802

F.2d at 1453; *In re Honda*, 168 F.R.D. at 540–41)). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] According to the WHO:

[A] site master file (SMF) is prepared by the pharmaceutical manufacturer and should contain specific information about the quality management policies and activities of the site, the production and/or quality control of pharmaceutical manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of a pharmaceutical operation is carried out on the site, an SMF need only describe those operations, e.g. analysis, packaging, etc.

. . . When submitted to a regulatory authority, the SMF should provide clear information on the manufacturer's good manufacturing practices (GMP)-related activities that can be useful in general supervision and in the efficient planning and undertaking of GMP inspections.

*Annex 14: WHO guidelines for drafting a site master file,*

[https://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/GuidelinesDraftingSiteMasterFileTRS961Annex14.pdf?ua=1](https://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesDraftingSiteMasterFileTRS961Annex14.pdf?ua=1). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

With respect to her authority to act on ZHP's behalf externally in its interest and in a reliable manner, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

Before the discovery of the contamination, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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In light of the above, and despite its conclusory Declaration to the contrary, the record shows that ZHP invested Ms. Hu with “general powers to exercise” [her] discretion and judgment in dealing with” valsartan, the quality of its manufacturing processes, its investigation of customer complaints, its response to such complaints, and its recent attempts to correct the nitrosamine contamination at issue in this case. *In re: Benicar*, 2016 WL 5817262, at \*3 n.12 (quoting Wright et al., *Federal Practice and Procedure* § 2103). The record also shows that ZHP places an exceptional trust in Ms. Hu to carry out these tasks and can therefore be relied upon to “give testimony at [its] demand.” *Id.* In fact, ZHP has already coordinated with Ms. Hu and scheduled her deposition. Lastly, Ms. Hu’s interests are closely aligned with ZHP, as her decisions since 2011 are a focal point of Plaintiffs’ case against ZHP. *Id.* The Court should consequently find that Ms. Hu is ZHP’s managing agent and deny ZHP’s motion for a protective order from her deposition.

**B. Fengyang (Xavier) Tang is ZHP’s Managing Agent**

The exceptional trust and authority that ZHP places in Xavier Tang is evidenced by the fact that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These documents contradict ZHP’s conclusory declaration that “Mr. Tang does not have independent decision making authority to bind ZHP,” “Mr. Tang cannot contract for API or finished dose,” and “Mr. Tang would not be expected to represent ZHP or to speak on behalf of ZHP on corporate matters or on valsartan manufacturing, quality, sales, or regulatory issues.” (Def.’s Ex. E). The Court should therefore find that Mr. Tang is ZHP’s managing agent and deny ZHP’s motion for a protective order from his deposition.

## II.

### **THE COURT HAS ALREADY REJECTED ZHP’S DUPLICATIVE TESTIMONY ARGUMENT**

ZHP argues that Yuelin Hu, Fengyan (Xavier) Tang, and Mi (Karen) Xu are duplicative deponents. After considering and rejecting this argument and ordering these depositions on December 31, 2020, the Court’s January 11, 2021 order did not grant ZHP leave to relitigate this issue. (12/31/2020 Order ¶ 3, ECF 704; 01/11/2021 Order ¶ 4, ECF 727).

In addition to ignoring the fact that the Court already ruled against this argument, ZHP claims that on January 5, 2021, it “reminded the Court that they had only been presented with the documents on which Plaintiff’s relied in support of the additional depositions.” (Def.’s Br. 8).

However, in support of its present motion, ZHP has only provided two outdated organization charts and a demonstrably false declaration. (*See* Part I). The Court should therefore decline to consider this part of ZHP's motion, and certainly should not allow reconsideration of the prior ruling where ZHP could have made all the same arguments and submitted the documents submitted here, at that time. However, out of an abundance of caution, Plaintiffs have demonstrated below that Yuelin Hu, Fengyan (Xavier) Tang, and Mi (Karen) Xu will all offer vital non-duplicative testimony in this case.<sup>7</sup>

Before getting into those specifics, the Court should be mindful that Plaintiffs are only scheduled to depose nineteen witnesses affiliated with six ZHP entities (ZHP, Syncores, Prinbury, Huahai US, Princeton, and Solco). In *Benicar*, the Court ordered at least thirty-eight depositions of the foreign defendant and its U.S. subsidiary. 2016 WL 6652358, at \*1. There, the Court wrote:

**The Court is not sympathetic to defendants' argument that the burden of the requested depositions is a material factor weighing in their favor. While being deposed might be unpleasant . . . , the burden they will endure is not materially different than that experienced by tens of thousands of witnesses. Further, the Court is mindful that the alleged burden to the two requested deponents is not weighed against the interests of just one plaintiff. Instead, the interests of approximately 1,800 plaintiffs are at issue.**

2016 WL 5817262, at \*6 n.16. This case is even more complicated and sprawling than *Benicar*. Here, Plaintiffs are asserting three distinct sets of claims against ZHP (economic loss, medical monitoring, and personal injury), and ZHP has far more subsidiaries involved in its wrongdoing

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<sup>7</sup> ZHP also asks this Court to deny the depositions at issue due to the health risks of traveling from China to Hong Kong during the pandemic. That argument has previously been addressed and the depositions are slated to take place in Hong Kong for all of the China resident witnesses. This is not a basis to preclude these depositions, which have already been ordered subject to only the managing agent issue.

than the primary defendant in *Benicar*. The Court should not limit Plaintiffs to less than half the depositions it ordered in *Benicar*.

**A. Yuelin Hu Will Provide Important Non-Duplicative Testimony**

Plaintiffs have already discussed Ms. Hu's central and authoritative role in [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (See above Part I.A). Moreover, nearly all the documents discussed above in Part I.A show no involvement from Ms. Hu's superiors or any other deponent, besides Peng Dong, who is not involved in ZHP's quality assurance activities. As this Court has already ruled, Ms. Hu's testimony is critical to Plaintiffs' case and must proceed as scheduled.

**B. Fengyang (Xavier) Tang Will Provide Important Non-Duplicative Testimony**

Mr. Tang had direct responsibility with communicating with ZHP's API customers.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs only opportunity to gather the information conveyed during these meetings is through sworn testimony.

**C. Mi (Karen) Xu Will Provide Important Non-Duplicative Testimony**

Similar to Mr. Tang, Ms. Xu likewise had intimate involvement with ZHP's API customers, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs are entitled to discover the information of what transpired [REDACTED], and deposing Ms. Xu provides Plaintiffs with this opportunity.

**CONCLUSION**

For the foregoing reasons, the Court should deny ZHP's motion for a protective order.

Dated: February 1, 2021

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 1, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater

Adam M. Slater